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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,742	12/31/2003	Raymond P. Warrell JR.	12475/50502	1835

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,742	WARRELL ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-150* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-150* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 9-16, 17-19, 20*, 21-71, and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is an antibody, classified in class 424, subclass 138.1.

II. Claims 1-5, 7-8 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a small molecule, classified in class 514, subclass 1.

III. Claims 1-5, 9-16, 72-80 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is an antisense molecule, classified in class 514, subclass 44.

IV. Claims 1-5, 9-16, 81, 82*, 83 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is an anti-telomerase agent, classified in class 514, subclass 1.

V. Claims 1-5, 84 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is an aptamer, classified in class 514, subclass 44.

VI. Claims 1-5, 9-16, 85-91 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a biological response modifier, classified in class 514, subclass 1.

VII. Claims 1-5, 9-16, 92 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a bisphosphonate, classified in class 514, subclass 75.

VIII. Claims 1-5, 9-16, 93-100 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a cytotoxic fusion protein, classified in class 514, subclass 2.

IX. Claims 1-5, 9-16, 101-106 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is an immunomodulating agent, classified in class 514, subclass 323.

X. Claims 1-5, 9-16, 107-108 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is an immunostimulating agent, classified in class 514, subclass 48.

XI. Claims 1-5, 109 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a molecular decoy, classified in class 514, subclass 1.

XII. Claims 1-5, 9-16, 110-114 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a molecular inhibitor, classified in class 514, subclass 1.

XIII. Claims 1-5, 9-16, 115-119 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a proteosome inhibitor, classified in class 514, subclass 19.

XIV. Claims 1-5, 9-16, 120-126, 130-132 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a protein kinase inhibitor, classified in class 514, subclass 252.18.

XV. Claims 1-5, 127-129 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is gefitnib, classified in class 514, subclass 183.

XVI. Claims 1-5, 9-16, 133-142 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is retinoid, classified in class 514, subclass 725.

XVII. Claims 1-5, 9-16, 143-144 and 149-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is a transcriptional factor, classified in class 514, subclass 2.

XVIII. Claims 1-5, 9-16 and 145-150, as specifically drawn to a treatment regimen for a mammal with neoplastic disease, comprising the steps of administering a therapeutic dose of a gallium compound and administering a therapeutic dose of at least one non-chemotherapeutic anticancer agent (NCAA), wherein the NCAA is an arsenic agent, classified in class 514, subclass 504.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). While the instant claims all require administration of a gallium compound and a second nonchemotherapeutic

anticancer agent, the nonchemotherapeutic agents are non-obvious structurally distinct molecules which demonstrates that each method has a different mode of operation. As such, each invention performs this function, e.g.., treating a neoplastic disease, using structurally and functionally divergent material. For these reasons the inventions of Groups I-XVIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups IV and VI-X have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV and VI-X.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claim 20, Group I, is generic to a plurality of disclosed patentably distinct species comprising the following antibodies: alemtuzumab, cetuximab, epratuzumab (LL2, hLL2), ... trastazumab, and anti-CD19/anti-CD3 single-chain bispecific antibody (bscCD19xCD3) which differ at least in chemical structure and antigen to which it binds such that one species can not be interchanged with another.

Claim 85, Group VI, is generic to a plurality of disclosed patentably distinct species comprising the following biologic response modifier: interleukin-2 (IL-2, aldesleukin), interleukin-11 (IL-11_, interleukin-12 (IL-12),and interferon-alpha2a (IFN-α2a) which differ at least in chemical structure and mechanism such that one species can not be interchanged with another.

Claim 149, Groups I-XVIII, is generic to a plurality of disclosed patentably distinct species comprising the following target molecule: CD52 antigen, epidermal growth factor receptor, ... CD19 antigen and CD3 antigen which differ at least in chemical structure such that one species can not be interchanged with another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
10/25/05